

REMARKS/ARGUMENTS

Claims 1-8 are canceled. Claims 9-23 have been added. Claims 9-23 are pending. Support for Claim 9 is found in Claim 1 as originally filed. Support for Claim 10 is found in Claim 2 as originally filed. Support for Claims 11, 12, and 13 is found in Claim 3 as originally filed. Support for Claims 14, 15, and 16 is found in the specification as originally filed. Support for Claim 17 is found in Claim 4 as originally filed. Support for Claim 18 is found on page 2, lines 21-22. Support for Claims 19-21 is found on page 2, lines 19-20. Support for Claim 22 is found in Claim 6 as originally filed. Support for Claim 23 is found in Claim 5 as originally filed. No new matter is believed to have been added.

Applicants thank Examiner George for the courteous and helpful discussion held with Applicants' representative on November 8, 2005. During this discussion, a new set of claims, Claims 9-23, were presented and it is understood that these amendments address the 35 U.S.C. §101 and §112, second paragraph issues. Applicants request the withdrawal of the objections to the original claims, the rejection under §112, second paragraph, and the rejection under §101.

The rejection of Claims 1, 2, 4, and 7 under 35 U.S.C. §102(e) in view of Hester (U.S. 2004/0077626 A1) is respectfully traversed.

During the above-noted discussion with the Examiner, Applicants' representative explained that the fosfomycin tromethamol in the present claims is not the same as the fosfomycin described in Hester. For support, a reference of record was presented to the Examiner that clearly shows the difference, and a copy is attached to this amendment for reference (See Barry et al., Antimicrobial Agents and Chemotherapy, June 1991, p. 1235-

1238). According to Barry, “fosfomycin tromethamine [is](previously fosfomycin tromethamol)” (see page 1235, second sentence of the second paragraph), and “fosfomycin tromethamol dissociates into two molecules, fosfomycin (molecular weight, 138) and tromethamine (molecular weight, 121)” (see page 1235, first sentence of the third paragraph). Thus, fosfomycin tromethamol and fosfomycin are distinct compounds. Because the fosfomycin disclosed in Hester is different from a fosfomycin tromethamol, the pharmaceutical compositions that stabilize fosfomycin tromethamol and the process for stabilizing such compositions are not disclosed by Hester. Accordingly, the withdrawal of the rejection of Claims 1, 2, 4, and 7 under §102(e) is requested.

The rejection of Claims 1-8 under 35 U.S.C. §103(a) in view of Shastri et al. (U.S. 2003/0078215 A1) and RxList Monographs (2002) is respectfully traversed.

As amended, Claim 17 of the present invention is directed to a pharmaceutical composition comprising a fosfomycin tromethamol and at least one stabilizing agent recited. As amended, Claim 9 recites a process for stabilizing a fosfomycin tromethamol in such pharmaceutical compositions. The present invention provides a solution to problems experienced in the storage of fosfomycin tromethamol, the preparation of pharmaceutical compositions of fosfomycin tromethamol, and the packaging of pharmaceutical compositions containing fosfomycin tromethamol due to the instability or reactivity of fosfomycin tromethamol.

Shastri discloses a composition comprising a fosfomycin and a number of stabilizing agents. However, Shastri does not disclose the claimed combination of a fosfomycin tromethamol and the stabilizing agents. As discussed above regarding the Hester rejection, fosfomycin tromethamol and fosfomycin are distinct compounds. The RxList is relied on to allege that certain dosage amount of fosfomycin tromethamine is taught (see page 6 of the

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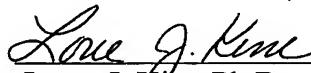
Office Action), and to conclude that the combined teachings of Shastri and the RxList result in the claimed invention. Applicants' disagree.

First, as Shastri describes fosfomycin and the RxList describes fosfomycin tromethamol, the teachings applicable to each chemically distinct compound are not simply combinable. Second, even if one assumed that the dosage amount in the RxList would be applicable to the Shastri's composition, since Shastri describes a different compound than the one recited in the claims, the combination of Shastri and the RxList does not render the claimed invention obvious. Thus, Applicants respectfully request the withdrawal of the rejection of Claims 1-8 under §103(a).

Applicants also request allowance of this application.

Respectfully submitted,

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